UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

MDL No. 1456

Master File No.: 01-CV-12257-PBS

THIS DOCUMENT RELATES TO:

State of Iowa v. Abbott Laboratories, et al.

Judge Patti B. Saris

DEFENDANTS MYLAN INC., MYLAN PHARMACEUTICALS INC. AND UDL LABORATORIES, INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT

Defendants Mylan Inc., formerly known as Mylan Laboratories Inc., Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. (collectively, "Mylan"), by their undersigned attorneys, as and for their Answer to Plaintiff's Complaint ("Complaint"), dated October 9, 2007, state as follows:

Mylan states that it is answering Plaintiff's allegations solely on behalf of itself, and only to the extent Plaintiff's allegations concern the alleged actions of Mylan, even when Plaintiff's allegations refer collectively to alleged conduct by Mylan and other persons or entities or refer to alleged conduct by "defendants" without further definition. To the extent the allegations in the Complaint refer to the alleged knowledge, conduct or actions of other persons or entities, Mylan is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

Mylan specifically denies any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint.

Mylan responds to the individual numbered paragraphs of the Complaint as follows:

- 1. Mylan denies the allegations in Paragraph 1 of the Complaint, except admits that Iowa purports to bring this action as alleged.
 - 2. Mylan denies the allegations in Paragraph 2 of the Complaint.
 - 3. Mylan denies the allegations in Paragraph 3 of the Complaint.
 - 4. Mylan denies the allegations in Paragraph 4 of the Complaint.
- 5. Mylan denies the allegations in the first, second, and third sentences of Paragraph 5 of the Complaint. Mylan denies the allegations in the fourth sentence of Paragraph 5 and refers the Court to the referenced materials for a full and complete statement of their contents.
 - 6. Mylan denies the allegations in Paragraph 6 of the Complaint.
 - 7. Mylan denies the allegations in Paragraph 7 of the Complaint.
- 8. Mylan denies the allegations in Paragraph 8 of the Complaint and refers the Court to the referenced statutes and related regulatory materials for a full and complete statement of their terms.
- 9. Mylan denies the allegations in the first sentence of Paragraph 9 of the Complaint and refers the Court to the referenced statutes and regulatory materials for a full and complete statement of their terms. Mylan denies the allegations in the second and third sentences of Paragraph 9.

- 10. Mylan denies the allegations in Paragraph 10 of the Complaint, except admits that Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. entered into rebate agreements with the Secretary of Health and Human Services, and refers the Court to both the referenced statute and the actual agreement for a full and complete statement of their terms.
- they pertain to Mylan, except admits that some pharmaceutical manufacturers report "Best Price" pursuant to the Medicaid Rebate Agreement and refers the Court to the referenced Medicaid Rebate agreement for a full and complete statement of its terms. To the extent the allegations in Paragraph 11 are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
 - 12. Mylan denies the allegations in Paragraph 12 of the Complaint.
 - 13. Mylan denies the allegations in Paragraph 13 of the Complaint.
- 14. To the extent the allegations in Paragraph 14 of the Complaint consist of legal conclusions, no response is required, and otherwise Mylan denies the allegations in Paragraph 14.
- 15. To the extent the allegations in Paragraph 15 of the Complaint consist of legal conclusions, no response is required, and otherwise Mylan refers the Court to the referenced cases for a full and complete statement of its contents.
 - 16. Mylan denies the allegations in Paragraph 16 of the Complaint.

- 17. Mylan denies the allegations in Paragraph 17 of the Complaint.
- 18. Mylan denies the allegations in Paragraph 18 of the Complaint, including the allegations contained in the referenced Exhibit B, except admits that Iowa purports to bring this action as alleged and Mylan further admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this action.
- 19. Mylan denies the allegations in Paragraph 19 of the Complaint, except admits that Iowa purports to bring the action as alleged.
 - 20. Mylan denies the allegations in Paragraph 20 of the Complaint.
- 21. To the extent the allegations in Paragraph 21 of the Complaint are directed at Mylan, Mylan admits only that it sold certain prescription drugs which were prescribed to Iowa citizens and reimbursed by Iowa payors, including Medicaid. To the extent the allegations in Paragraph 21 are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
- 22–31. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 22 through 31 of the Complaint and, therefore, denies those allegations.
- 32. Mylan denies the allegations in Paragraph 32 of the Complaint, including all subparagraphs, except admits that Dey, Inc. and Dey, L.P. do business at 2751 Napa Valley Corporate Drive, Napa, CA 94558 and that Dey, L.P. is engaged in the business of manufacturing and selling pharmaceuticals.

- 33–43. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 33 through 43 of the Complaint and, therefore, denies those allegations.
- 44(a). Mylan denies the allegations in Paragraph 44(a) of the Complaint except admits that Mylan Laboratories Inc. is a Pennsylvania corporation whose principal place of business is located at 1500 Corporate Drive, Canonsburg, Pennsylvania, 15317.
 - 44(b). Mylan admits the allegations in Paragraph 44(b) of the Complaint.
- 44(c). Mylan denies the allegations of Paragraph 44(c) of the Complaint except admits that UDL Laboratories, Inc. ("UDL") is a wholly owned subsidiary of Mylan Inc. (f/k/a Mylan Laboratories Inc.) and is an Illinois corporation whose principal place of business is located at 1718 Northrock Court, Rockford, Illinois 61103 and further admits that UDL engages in the business of selling pharmaceuticals.
- 45–58. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 45 through 58 of the Complaint and, therefore, denies those allegations.
- 59. Mylan denies the allegations in paragraph 59 of the Complaint except admits that Plaintiff seeks the recovery alleged.
 - 60. Mylan denies the allegations in paragraph 60 of the Complaint.
 - 61. Mylan denies the allegations in paragraph 61 of the Complaint.

- 62. Mylan denies the allegations in Paragraph 62 of the Complaint and refers the Court to the referenced statutes for a full and complete statement of their terms.
- 63. Mylan denies the allegations in Paragraph 63 of the Complaint and refers the Court to the referenced statutes for a full and complete statement of their terms.
- 64. Mylan denies the allegations in Paragraph 64 of the Complaint and refers the Court to the referenced statutes for a full and complete statement of their terms.
- 65. Mylan denies the allegations in Paragraph 65 of the Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.
- 66. Mylan denies the allegations in Paragraph 66 of the Complaint, except admits that prescription drugs in the United States are assigned a National Drug Code ("NDC") and further admits that the United States Food and Drug Administration publishes NDCs for each of the dosage forms and package sizes of a prescription drug.
- 67. Mylan denies the allegations in Paragraph 67 of the Complaint and refers the Court to the referenced regulations for a full and complete statement of their terms.
- 68. Mylan denies the allegations in Paragraph 68 of the Complaint and refers the Court to the referenced report for a full and complete statement of its contents.
- 69. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69 of the Complaint and, therefore, denies those allegations.

- 70. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70 of the Complaint and, therefore, denies those allegations.
- 71. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 71 of the Complaint and, therefore, denies those allegations.
 - 72. Mylan denies the allegations in Paragraph 72 of the Complaint.
- 73–77. Mylan denies the allegations in Paragraphs 73 through 77 of the Complaint and refers the Court to the referenced statutes and regulatory materials for a full and complete statement of their terms.
- 78. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 78 of the Complaint and, therefore, denies those allegations.
- 79. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 79 of the Complaint and, therefore, denies those allegations.
- 80. Mylan denies the allegations in Paragraph 80 of the Complaint, including the allegations contained in the referenced Exhibit B, except admits that Iowa purports to bring this action as alleged and Mylan further admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this action.

- 81. Mylan denies the allegations in the first sentence of Paragraph 81 of the Complaint except admits that certain publishing services publish and report AWP. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the second and third sentences of Paragraph 81, and, therefore, denies those allegations.
 - 82. Mylan denies the allegations in Paragraph 82 of the Complaint.
 - 83. Mylan denies the allegations in Paragraph 83 of the Complaint.
 - 84. Mylan denies the allegations in Paragraph 84 of the Complaint.
- 85. Mylan denies the allegations in Paragraph 85 of the Complaint except admits that Exhibit A purports to allege certain information regarding the prescription drugs at issue.
 - 86. Mylan denies the allegations in Paragraph 86 of the Complaint.
 - 87. Mylan denies the allegations in Paragraph 87 of the Complaint.
 - 88. Mylan denies the allegations in Paragraph 88 of the Complaint.
 - 89. Mylan denies the allegations in Paragraph 89 of the Complaint.
 - 90. Mylan denies the allegations in Paragraph 90 of the Complaint.
 - 91. Mylan denies the allegations in Paragraph 91 of the Complaint.
 - 92. Mylan denies the allegations in Paragraph 92 of the Complaint.
 - 93. Mylan denies the allegations in Paragraph 93 of the Complaint.

- 94. Mylan denies the allegations in Paragraph 94 of the Complaint.
- 95. Mylan denies the allegations in Paragraph 95 of the Complaint insofar as they pertain to Mylan, and to the extent the allegations in Paragraph 95 of the Complaint are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
- 96. Mylan denies the allegations in Paragraph 96 of the Complaint insofar as they pertain to Mylan, and to the extent the allegations in Paragraph 96 of the Complaint are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
 - 97. Mylan denies the allegations in Paragraph 97 of the Complaint.
- 98. Mylan denies the allegations in the first sentence of Paragraph 98 of the Complaint except admits that certain publishing services publish and report AWP. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the second, third, and fourth sentences of Paragraph 98, and, therefore, denies those allegations.
- 99. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 99, and, therefore, denies those allegations.
 - 100. Mylan denies the allegations in Paragraph 100 of the Complaint.
- 101. Mylan denies the allegations in Paragraph 101 of the Complaint, including the allegations in the referenced Exhibit C, except admits that Exhibit C purports to allege certain information regarding the prescription drugs at issue.

- Mylan denies the allegations in the of Paragraph 102 of the Complaint and refers the Court to the referenced regulation for a full and complete statement of its terms.
- Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 103, and, therefore, denies those allegations.
 - 104. Mylan denies the allegations in Paragraph 104 of the Complaint.
- Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 105, and, therefore, denies those allegations.
 - 106. Mylan denies the allegations in Paragraph 106 of the Complaint.
 - 107. Mylan denies the allegations in Paragraph 107 of the Complaint.
- 108. Mylan denies the allegations in Paragraph 108 of the Complaint, including the allegations contained in the referenced Exhibit B.
- 109. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first, second, third, and fourth sentences of Paragraph 109, and, therefore, denies those allegations. Mylan denies the allegations in the fifth sentence of Paragraph 109.
- Mylan denies the allegations in Paragraph 110 and refers the Court to the referenced statute for a full and complete statement of its terms.
- Mylan denies the allegations in Paragraph 111 of the Complaint, except admits that Mylan Pharmaceuticals Inc. and UDL entered into rebate agreements with the

Secretary of Health and Human Services and refers the Court to those agreements for a full and complete statement of their terms.

- Mylan denies the allegations in Paragraph 112 of the Complaint, except admits that Mylan Pharmaceuticals Inc. and UDL entered into rebate agreements with the Secretary of Health and Human Services and refers the Court to those agreements for a full and complete statement of their terms.
- 113. Mylan denies the allegations in Paragraph 113 and refers the Court to the referenced statute and Medicaid Rebate Agreements for a full and complete statement of their terms.
- 114. Mylan denies the allegations in Paragraph 114 and refers the Court to the referenced statute and Medicaid Rebate Agreements for a full and complete statement of their terms.
- 115. Mylan denies the allegations in Paragraph 115 of the Complaint, except admits that Iowa's Federal Rebate claims purport to concern only those rebates paid by brand manufacturers.
- 116. Mylan denies the allegations in Paragraph 116 and refers the Court to the referenced statute and Medicaid Rebate Agreements for a full and complete statement of their terms.
- Mylan denies the allegations in Paragraph 117 of the Complaint, except admits that Mylan Pharmaceuticals Inc. and UDL entered into rebate agreements with the

Secretary of Health and Human Services and refers the Court to those agreements for a full and complete statement of their terms.

- 118. Mylan denies the allegations in Paragraph 118 and refers the Court to the referenced statute and Medicaid Rebate Agreements for a full and complete statement of their terms.
- 119. Mylan denies the allegations in Paragraph 119 and refers the Court to the referenced statute and Medicaid Rebate Agreements for a full and complete statement of their terms.
- Mylan denies the allegations in Paragraph 120 and refers the Court to the referenced statute for a full and complete statement of its terms.
- 121. Mylan denies the allegations in Paragraph 121 of the Complaint, except admits that Mylan Pharmaceuticals Inc. and UDL entered into rebate agreements with the Secretary of Health and Human Services and refers the Court to those agreements for a full and complete statement of their terms.
- 122. Mylan denies the allegations in Paragraph 122 of the Complaint, except admits that the Secretary of Health and Human Services reported URAs to Iowa, and refers the Court to the relevant statutes and Medicaid Rebate Agreements for a full and complete statement of their terms.
- 123. Mylan denies the allegations in Paragraph 123 and refers the Court to the referenced statute and Medicaid Rebate Agreements for a full and complete statement of their terms.

- 124. Mylan denies the allegations in Paragraph 124 and refers the Court to the referenced statute and Medicaid Rebate Agreements for a full and complete statement of their terms.
- 125. Mylan denies the allegations in Paragraph 125 and refers the Court to the referenced statute and Medicaid Rebate Agreements for a full and complete statement of their terms.
- 126. Mylan denies the allegations in Paragraph 126 of the Complaint insofar as they pertain to Mylan, and to the extent the allegations in Paragraph 126 are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
 - 127. Mylan denies the allegations in Paragraph 127 of the Complaint.
- 128. Mylan denies the allegations in the first sentence of Paragraph 128 of the Complaint. Mylan denies the allegations in the second sentence of Paragraph 128 and refers the Court to the referenced agreement for a full and complete statement of its terms. Mylan denies the allegations in the third sentence of Paragraph 128.
- 129. Mylan denies the allegations in the first sentence of Paragraph 129 of the Complaint insofar as they pertain to Mylan, and to the extent the allegations in Paragraph 129 are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mylan denies the allegations in the second sentence of Paragraph 129 and refers the Court to the referenced statute for a full and complete statement of its terms. Mylan denies having knowledge or

information sufficient to form a belief as to the truth of the allegations in the third and fourth sentences of Paragraph 129, and, therefore, denies those allegations.

- 130. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 130 of the Complaint and, therefore, denies those allegations, but refers the Court to the referenced letter for a full and complete statement of its contents.
- Mylan denies the allegations in Paragraph 131 and refers the Court to the referenced statute for a full and complete statement of its terms.
- 132. Mylan denies the allegations in Paragraph 132 of the Complaint insofar as they pertain to Mylan, and to the extent the allegations in Paragraph 132 are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
 - 133. Mylan denies the allegations in Paragraph 133 of the Complaint.
- 134. Mylan denies the allegations in the first sentence of Paragraph 134 of the Complaint. Mylan denies the allegations in the second sentence of Paragraph 134 and refers the Court to the referenced congressional hearing transcript for a full and complete statement of its contents.
- 135. Mylan denies the allegations in Paragraph 135 and refers the Court to the referenced statute and Medicaid Rebate Agreements for a full and complete statement of their terms.

- 136. Mylan denies the allegations in Paragraph 136 of the Complaint insofar as they pertain to Mylan. To the extent the allegations in Paragraph 136 are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
- 137. Mylan denies the allegations in Paragraph 137 of the Complaint insofar as they pertain to Mylan. To the extent the allegations in Paragraph 137 are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
- as they pertain to Mylan, and to the extent the allegations in Paragraph 138 are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mylan refers the Court to the referenced congressional hearing transcript for a full and complete statement of its contents.
- as they pertain to Mylan, and to the extent the allegations in Paragraph 139 are directed to parties other than Mylan, Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mylan refers the Court to the referenced congressional hearing transcript for a full and complete statement of its contents.
 - 140. Mylan denies the allegations in Paragraph 140 of the Complaint.
 - 141. Mylan denies the allegations in Paragraph 141 of the Complaint.

- Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 142 of the Complaint and, therefore, denies those allegations.
- Mylan denies the allegations in Paragraph 143 of the Complaint, including the allegations contained in the referenced Exhibit B.
- 144. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first, second, and third sentences of Paragraph 144 of the Complaint and, therefore, denies those allegations. Mylan denies the allegations in the fourth and fifth sentences of Paragraph 144.
- Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 145 of the Complaint.
 - 146. Mylan denies the allegations in Paragraph 146 of the Complaint.
 - 147. Mylan denies the allegations in Paragraph 147 of the Complaint.
 - 148. Mylan denies the allegations in Paragraph 148 of the Complaint.
 - 149. Mylan denies the allegations in Paragraph 149 of the Complaint.
 - 150. Mylan denies the allegations in Paragraph 150 of the Complaint.
- 151. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first, second, third, and fourth sentences of Paragraph 151 of the Complaint and, therefore, denies those allegations. Mylan denies the allegations in the fifth sentence of Paragraph 151.

- 152. Mylan denies the allegations in Paragraph 152 and refers the Court to the referenced congressional hearing transcript for a full and complete statement of its contents.
 - 153. Mylan denies the allegations in Paragraph 153 of the Complaint.
 - 154. Mylan denies the allegations in Paragraph 154 of the Complaint.
- 155. Mylan denies the allegations in Paragraph 155 of the Complaint and refers the Court to the referenced report for a full and complete statement of its contents.
 - 156. Mylan denies the allegations in Paragraph 156 of the Complaint.
- 157. Mylan denies the allegations in Paragraph 157 of the Complaint and refers the Court to the referenced report for a full and complete statement of its contents.
 - 158. Mylan denies the allegations in Paragraph 158 of the Complaint.
- 159. Mylan denies the allegations in Paragraph 159 of the Complaint, except admits that Mylan Pharmaceuticals and UDL participates in the federal Medicaid program through which Iowa is obligated to reimburse providers for Mylan Pharmaceuticals' and UDL's drugs.
- 160. Mylan denies the allegations in Paragraph 159 of the Complaint, except admits that Mylan Pharmaceuticals and UDL participates in the federal Medicaid program through which Iowa is obligated to reimburse providers for Mylan Pharmaceuticals' and UDL's drugs.
 - 161. Mylan denies the allegations in Paragraph 161 of the Complaint.

- 162. Mylan denies the allegations in Paragraph 162 of the Complaint.
- 163. To the extent the allegations in the first sentence of Paragraph 163 of the Complaint consist of legal conclusions, no response is required, and otherwise Mylan denies the allegations. Mylan denies the allegations in the second sentence of Paragraph 163.
- Mylan denies the allegations in Paragraph 164 of the Complaint and refers the Court to the cited cases for a full and complete statement of their contents.
 - 165. Mylan denies the allegations in Paragraph 165 of the Complaint.
 - 166. Mylan denies the allegations in Paragraph 166 of the Complaint.
- 167. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 167 of the Complaint and, therefore, denies those allegations. Mylan denies the allegations in the second sentence of Paragraph 167.
 - 168. Mylan denies the allegations in Paragraph 168 of the Complaint.
 - 169. Mylan denies the allegations in Paragraph 169 of the Complaint.
 - 170. Mylan denies the allegations in Paragraph 170 of the Complaint.
 - 171. Mylan denies the allegations in Paragraph 171 of the Complaint.
- 172. Mylan denies the allegations in the first sentence of Paragraph 172 of the Complaint except admits that Exhibit B purports to identify the prescription drugs at issue.

 Mylan denies having knowledge or information sufficient to form a belief as to the truth of the

allegations in the second sentence of Paragraph 172 and, therefore, denies those allegations.

Mylan denies the allegations in the third sentence of Paragraph 172, except admits that Exhibit B purports to allege certain information regarding the prescription drugs at issue.

- 173. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 173 of the Complaint and, therefore, denies those allegations, except admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this action.
- Mylan denies the allegations in Paragraph 174 of the Complaint, except admits that Exhibit B purports to allege certain information regarding the prescription drugs at issue.
 - 175. Mylan denies the allegations in Paragraph 175 of the Complaint.
 - 176. Mylan denies the allegations in Paragraph 176 of the Complaint.
 - 177. Mylan denies the allegations in Paragraph 177 of the Complaint.
 - 178. Mylan denies the allegations in Paragraph 178 of the Complaint.
- 179. Mylan denies the allegations in Paragraph 179 of the Complaint, except admits that Mylan entered into contracts with certain purchasers and refers the Court to those contracts for a full and complete statement of their terms.
- 180. Mylan denies the allegations in Paragraph 180 of the Complaint, including the allegations contained in the referenced Exhibit A.

- 181–466. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 181 through 466 of the Complaint and, therefore, denies those allegations.
- 467. Mylan denies the allegations in the first sentence of Paragraph 467 of the Complaint, including the allegations contained in the referenced Exhibit A. Mylan denies the allegations in the second sentence of Paragraph 467, except admits that Exhibit B-23 purports to list the prescription drugs at issue in this action for Mylan. Mylan denies the allegations in Paragraph 467, but admits that Plaintiff has alleged claims without basis and as to which no relief should be granted.
- 468. Mylan denies the allegations in Paragraph 468 of the Complaint, including the allegations contained in the referenced Exhibit B.
- 469. Mylan denies the allegations in Paragraph 469 of the Complaint, including the allegations in the chart following Paragraph 469, and refers the Court to the referenced First DataBank information for a full and complete statement of its contents.
 - 470. Mylan denies the allegations in Paragraph 470 of the Complaint.
 - 471. Mylan denies the allegations in Paragraph 471 of the Complaint.
- 472. Mylan denies the allegations in Paragraph 472 of the Complaint except Mylan admits that it has responded to written requests for information from the House Energy and Commerce Committee without any admission or finding of fault or liability.
 - 473. Mylan denies the allegations in Paragraph 473 of the Complaint.

- 474-613. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 474-613 of the Complaint and, therefore, denies those allegations.
- 614. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 614 of the Complaint and, therefore, denies those allegations. Mylan denies the allegations in the second sentence of Paragraph 614.
 - 615. Mylan denies the allegations in Paragraph 615 of the Complaint.
 - 616. Mylan denies the allegations in Paragraph 616 of the Complaint.
 - 617. Mylan denies the allegations in Paragraph 617 of the Complaint.
 - 618. Mylan denies the allegations in Paragraph 618 of the Complaint.
 - 619. Mylan denies the allegations in Paragraph 619 of the Complaint.
 - 620. Mylan denies the allegations in Paragraph 620 of the Complaint.
 - 621. Mylan denies the allegations in Paragraph 621 of the Complaint.
 - 622. Mylan denies the allegations in Paragraph 622 of the Complaint.
 - 623. Mylan denies the allegations in Paragraph 623 of the Complaint.
 - Mylan denies the allegations in Paragraph 624 of the Complaint.
 - 625. Mylan denies the allegations in Paragraph 625 of the Complaint.

- 626. Mylan denies the allegations in Paragraph 626 of the Complaint.
- 627. Mylan denies the allegations in Paragraph 627 of the Complaint.
- 628. Mylan denies the allegations in Paragraph 628 of the Complaint.
- 629. Mylan denies the allegations in Paragraph 629 of the Complaint.
- 630. Mylan denies the allegations in Paragraph 630 of the Complaint and refers the Court to the referenced article for a full and complete statement of its contents.
 - 631. Mylan denies the allegations in Paragraph 631 of the Complaint.
 - 632. Mylan denies the allegations in Paragraph 632 of the Complaint.

COUNT I

- 633. Answering Paragraph 633 of the Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 through 632 of the Complaint.
- 634–642. This Count was dismissed by this Court on August 19, 2008.

 Accordingly, Mylan is not required to respond to Paragraphs 634 through 642 of the Complaint.

 To the extent a response is required, Mylan denies all allegations contained within Count I of the Complaint.

COUNT II

- 643. Answering Paragraph 643 of the Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 through 642 of the Complaint
- 644. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 644 of the Complaint, except admits that Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. entered into rebate agreements with the Secretary of Health and Human Services and refers the Court to those agreements for a full and complete statement of their terms.
- 645. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 645 of the Complaint, except admits that Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. entered into rebate agreements with the Secretary of Health and Human Services and refers the Court to those agreements for a full and complete statement of their terms.
- 646. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 646 of the Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.
- 647. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 647 of the Complaint and, therefore, denies those allegations.

- 648. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 648 of the Complaint, except admits that Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. entered into rebate agreements with the Secretary of Health and Human Services and refers the Court to those agreements for a full and complete statement of their terms.
- 649. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 649 of the Complaint.
- 650. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 650 of the Complaint.
- 651. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 651 of the Complaint.

COUNT III

- 652. Answering Paragraph 652 of the Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 through 651 of the Complaint
- 653. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 653 of the Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.

- 654. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 654 of the Complaint.
- 655. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 655 of the Complaint.
- 656. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 656 of the Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.
- 657. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 657 of the Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.

COUNT IV

- 658. Answering Paragraph 658 of the Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 through 657 of the Complaint
- 659. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 659 of the Complaint.

- 660. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 660 of the Complaint.
- 661. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 661 of the Complaint.
- 662. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 662 of the Complaint.

COUNT V

- 663. Answering Paragraph 663 of the Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 through 662 of the Complaint
- 664. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 664 of the Complaint.
- 665. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 665 of the Complaint.

666. This Count was dismissed in part by this Court on August 19, 2008. To the extent a response is required, Mylan denies the allegations in Paragraph 666 of the Complaint.

Mylan denies that the State is entitled to a judgment or any other relief as requested in the unnumbered "WHEREFORE" paragraph following Paragraph 666 of the Complaint.

- Mylan denies the State is entitled to judgment as requested in Paragraph 667 of the Complaint.
- 668. Mylan denies the State is entitled to judgment as requested in Paragraph 668 of the Complaint.
- 669. Mylan denies the State is entitled to judgment as requested in Paragraph 669 of the Complaint.
- 670. Mylan denies the State is entitled to judgment as requested in Paragraph 670 of the Complaint.
- Mylan denies the State is entitled to judgment as requested in Paragraph 671 of the Complaint.
- Mylan denies the State is entitled to judgment as requested in Paragraph 672 of the Complaint.
- 673. Mylan denies the State is entitled to judgment as requested in Paragraph 673 of the Complaint.

- 674. Mylan denies the State is entitled to judgment as requested in Paragraph 674 of the Complaint.
- 675. Mylan denies the State is entitled to judgment as requested in Paragraph 675 of the Complaint.

AFFIRMATIVE AND OTHER DEFENSES

First Defense

The Complaint fails to state a claim against Mylan upon which relief can be granted.

Second Defense

The Complaint fails to satisfy the pleading requirements of Rule 8(a) of the Federal Rules of Civil Procedure.

Third Defense

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Mylan as alleged in the Complaint.

Fourth Defense

Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations, and Plaintiff is not entitled to any tolling of any limitations period.

Fifth Defense

Plaintiff is estopped from claiming entitlement to the sum it seeks because it has known throughout the relevant time period, from various public sources, including government reports provided to Plaintiff, that the AWPs published in industry sources were not what Plaintiff now claims them to have been. Plaintiff was aware that the reimbursement rates it was using to

reimburse providers were greater than the estimated acquisition cost of these drugs, and knowingly set its reimbursement rates higher than estimated acquisition cost.

Sixth Defense

Plaintiff fails to allege with particularity facts to support the fraud and/or fraudulent concealment allegations against Mylan as required by Rule 9(b) of the Federal Rules of Civil Procedure.

Seventh Defense

During the relevant time period, the Iowa Medicaid Program did not regard AWP as anything other than a list or "sticker" price which it discounted for both branded and generic drugs when determining reimbursement rates.

Eighth Defense

Plaintiff's claims are barred, in whole or in part, by the doctrines of laches, estoppel, waiver, and unclean hands.

Ninth Defense

Plaintiff's claims are barred to the extent that the claims involve drugs reimbursed without reference to AWP or WAC.

Tenth Defense

Plaintiff's claims are barred, in whole or in part, because Mylan's alleged statements, actions, or omissions were not the proximate cause of any alleged loss by Plaintiff.

Eleventh Defense

Plaintiff was negligent, careless, committed willful misconduct or was otherwise at fault in and about the matter referred to in the Complaint and such conduct on the part of Plaintiff caused and contributed to the injury complained of, if any actually occurred.

Twelfth Defense

Plaintiff directed, ordered, approved and/or ratified Mylan's conduct, and Plaintiff is, therefore, barred from asserting any claims based thereon.

Thirteenth Defense

Any and all actions taken by Mylan with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

Moreover, publishers, including First Data Bank, rather than Mylan, determine the AWP that they publish for drugs.

Fourteenth Defense

Plaintiff's claims against Mylan are barred because Mylan has complied with all applicable regulations of the federal government and the State of Iowa.

Fifteenth Defense

Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff, if any, were the result of its own conduct or intervening or superseding acts or omissions of third parties.

Sixteenth Defense

Plaintiff's claims against Mylan for damages are barred, in whole or in part, because Plaintiff failed to mitigate and/or neglected to minimize its damages, and its failure to mitigate damages should proportionately reduce its recovery and the allocation of any fault, if any exists, attributable to Mylan.

Seventeenth Defense

Plaintiff receives funding from the federal government for a percentage of the prescription drug reimbursements made under the Iowa Medicaid program. Any of Plaintiff's recovery should be substantially if not entirely set off by appropriate percentages of those

amounts and should also be reduced by any benefits and rebates provided by Mylan. Plaintiff's claims against Mylan for damages are barred, in whole or in part, because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

Eighteenth Defense

Mylan is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff with respect to the same alleged injuries.

Nineteenth Defense

Plaintiff's claims for damages against Mylan are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for pharmaceuticals manufactured, marketed and sold by Mylan after the filing of Plaintiff's complaint and after first learning of the information that forms the basis for the allegations in Plaintiff's complaint.

Twentieth Defense

Any damages recovered by Plaintiff must be limited by the applicable statutory ceilings on recoverable damages.

Twenty-First Defense

Plaintiff fails to state a claim against Mylan sufficient to support an award for costs of the suit, statutory penalties or damages, attorneys' fees and/or legal fees.

Twenty-Second Defense

Plaintiff's claims are barred, in whole or in part, by the doctrines of mistake and mutual mistake.

Twenty-Third Defense

The civil penalties sought against Mylan cannot be sustained because an award of the civil penalties sought by Plaintiff would violate the United States Constitution, Excessive Fines Clause of the Eighth Amendment, U.S. Const. amend. VIII, and the Due Process Clauses of the Fifth and Fourteenth Amendments, U.S. Const. amend. V and XIV, and the analogous provisions in the Constitution of the State of Iowa.

Twenty-Fourth Defense

Plaintiff's claims are barred, in whole or in part, because they violate Mylan's rights under the Due Process and Ex Post Facto clauses of the United States Constitution and the analogous provisions of the Constitution of the State of Iowa insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Twenty-Fifth Defense

The granting of relief prayed for in Plaintiff's Complaint is unconstitutional under the United States Constitution and Constitution of the State of Iowa in that it violates Due Process and Equal Protection guarantees, places an undue burden on interstate commerce, and violates Constitutional proscriptions against excessive fines.

Twenty-Sixth Defense

The granting of the relief prayed for in Plaintiff's Complaint is unconstitutional in that it would violate Mylan's right of commercial speech under the United States Constitution and Constitution of the State of Iowa.

Twenty-Seventh Defense

Plaintiff has failed to join all persons and parties necessary for a just adjudication of the controversy.

Twenty-Eighth Defense

Any or all causes of action in Plaintiff's Complaint are barred because of the lack of privity between Plaintiff and Mylan.

Twenty-Ninth Defense

Any or all causes of action in Plaintiff's Complaint are barred because the statutes upon which Plaintiff relies are vague and ambiguous.

Thirtieth Defense

Plaintiff's claims for injunctive relief against Mylan are barred by the doctrines of *in pari delicto* and/or unclean hands.

Thirty-First Defense

Plaintiff's claims are barred, in whole or in part, because Mylan did not make any statements to Plaintiff. As to any statement asserted against Mylan that Plaintiff claims to be false or misleading, Mylan had no reasonable grounds to believe, and did not believe at the time such statements were made, that the statements were false or misleading.

Thirty-Second Defense

Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Thirty-Third Defense

Plaintiff's claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Thirty-Fourth Defense

Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

Thirty-Fifth Defense

Mylan did not owe any duty to Plaintiff and did not breach any duty owed to Plaintiff.

Thirty-Sixth Defense

Plaintiff's claims are barred, in whole or in part, by the government contractor and similar defenses because the reimbursement system, including the use of AWP in excess of actual average prices, was designed and approved by Plaintiff, along with the federal government and the State of Iowa, to serve its purposes.

Thirty-Seventh Defense

Plaintiff's claims against Mylan are barred, in whole or in part, because it has suffered no damages as a result of the matters alleged in the Complaint.

Thirty-Eighth Defense

Plaintiff's claims for damages are barred, in whole or in part, because its alleged damages, if any, are speculative and because of the impossibility of the ascertainment and allocation of those alleged damages.

Thirty-Ninth Defense

To the extent equitable relief is sought, such claims cannot be sustained because the Plaintiff has an adequate remedy at law.

Fortieth Defense

Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

Forty-First Defense

Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit to recover Medicaid expenditures or to seek injunctive relief.

Forty-Second Defense

Plaintiff's claims against Mylan for injunctive relief were mooted by the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

Forty-Third Defense

To the extent punitive damages are sought, Plaintiff's punitive damages claims against Mylan: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Mylan; (3) cannot be sustained because the laws regarding the standards for determining liability for and the amount of punitive damages fail to give Mylan prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of Mylan's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Iowa; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Mylan's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and laws of the State of Iowa; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Mylan for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Mylan's products would constitute impermissible multiple punishments for the same wrong, in violation of Mylan's Due Process and Equal Protection rights guaranteed by the Fifth and

Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law, and statutory laws of the State of Iowa; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Mylan's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Iowa; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Mylan the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Mylan's rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Iowa.

Forty-Fourth Defense

To the extent punitive damages are sought, Plaintiff's claims for punitive damages against Mylan cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and

corporate status of Mylan; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Mylan's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law, and public policies of the State of Iowa.

Forty-Fifth Defense

To the extent punitive damages are sought, Plaintiff's claims for punitive damages against Mylan cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Mylan's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Mylan's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law, and public policies of the State of Iowa.

Forty-Sixth Defense

Plaintiff's claims are barred, in whole or in part, because Mylan did not retain any money belonging to the State of Iowa as a result of any alleged overpayments.

Forty-Seventh Defense

Subject to confirmation during discovery, Mylan hereby reserves those affirmative defenses required to be specifically pled under Rule 8(b) of the Federal Rules of Civil Procedure not specifically pled above and incorporates them as if fully set forth in separate

paragraphs. Mylan reserves the right to amend its answer to assert additional affirmative defenses and to supplement those asserted herein upon discovery of further information regarding the claims asserted in the Complaint. These additional defenses cannot be asserted at this time because of the lack of detail in the Complaint concerning Plaintiff's claims.

Forty-Eighth Defense

Mylan Laboratories Inc. does not and has not conducted any business in Iowa and there is no basis for personal jurisdiction over Mylan Laboratories Inc. under Iowa law, and personal jurisdiction over Mylan Laboratories Inc. would be improper under the United States Constitution.

Forty-Ninth Defense

The Plaintiff's claims are barred, in whole or in part, by the settlement agreement in connection with FTC v. Mylan Laboratories Inc., et al., C.A. No. 98-CV-03114-TFH (D.D.C.) and State of Connecticut v. Mylan Laboratories Inc., et al., C.A. No. 98-CV-03115-TFH (D.D.C.).

Fiftieth Defense

The Plaintiff's claims are barred, in whole or in part, by the release of claims in connection with FTC v. Mylan Laboratories Inc., et al., C.A. No. 98-CV-03114-TFH (D.D.C.) and State of Connecticut v. Mylan Laboratories Inc., et al., C.A. No. 98-CV-03115-TFH (D.D.C.).

Fifty-First Defense

The Plaintiff's claims are barred, in whole or in part, by an accord and satisfaction between Mylan and the State of Iowa in connection with *FTC v. Mylan Laboratories Inc.*, *et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc.*, *et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

Fifty-Second Defense

The Plaintiff's claims are barred, in whole or in part, by Mylan's payment in connection with FTC v. Mylan Laboratories Inc., et al., C.A. No. 98-CV-03114-TFH (D.D.C.) and State of Connecticut v. Mylan Laboratories Inc., et al., C.A. No. 98-CV-03115-TFH (D.D.C.).

Fifty-Third Defense

The Plaintiff's claims are barred, in whole or in part, by the waiver of claims in connection with FTC v. Mylan Laboratories Inc., et al., C.A. No. 98-CV-03114-TFH (D.D.C.) and State of Connecticut v. Mylan Laboratories Inc., et al., C.A. No. 98-CV-03115-TFH (D.D.C.).

Fifty-Fourth Defense

To the extent Plaintiff has obtained or obtains recovery in any other action or proceeding predicated on the same factual allegations, it is barred from seeking recovery against Mylan based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel and the prohibition on double recovery for the same injury.

Fifty-Fifth Defense

Some or all of the Plaintiff's claims against Mylan arise from the State of Iowa's failure to follow its federal and state statutory and regulatory obligations to properly establish appropriate reimbursement rates.

Fifty-Sixth Defense

The Plaintiff's claims are barred, in whole or in part, because the Plaintiff has not suffered any actual injury or damage as a result of any conduct alleged as a basis of this lawsuit.

Fifty-Seventh Defense

The Plaintiff's claims are barred, in whole or in part, because Mylan's alleged conduct was reasonable and based on independent, legitimate business and economic justifications.

Fifty-Eighth Defense

The Plaintiff's claims are barred, in whole or in part, because any and all of Mylan's actions alleged by the Plaintiff were lawful, justified, pro-competitive, carried out in furtherance of Mylan's legitimate business interests, and constitute bona fide business competition.

Fifty-Ninth Defense

The Plaintiff's claims are barred, in whole or in part, by the First Amendment of the United States Constitution and the analogous provisions of the Constitution of the State of Iowa.

Sixtieth Defense

The Plaintiff's claims against Mylan are misjoined with Plaintiff's claims against other defendants and must be severed.

Sixty-First Defense

Plaintiff's claims against Mylan are barred, in whole or in part, by the existence of and terms of the written rebate agreement between Mylan and the Secretary of the Department of Health and Human Services ("HHS"), on behalf of HHS and all States, including Iowa, entitled, "Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturer Identified in Section XI of this Agreement", which was entered into pursuant to 42 U.S.C. § 1396r-8.

Sixty-Second Defense

Mylan hereby gives notice that it intends to rely upon any other additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense. Mylan also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of a state other than Iowa and/or any other State which is or becomes relevant in the course of this multidistrict litigation.

Sixty-Third Defense

Mylan hereby adopts and incorporates by reference, as if fully set forth herein, any affirmative defenses listed by any other defendant in its answer to Plaintiff's Complaint to the extent that such defenses are factually and/or legally consistent with Mylan's position.

WHEREFORE, Mylan prays for judgment: (i) dismissing the Complaint in its entirety; (ii) awarding to Mylan costs and fees incurred in this action; and (iii) granting to Mylan such other and additional relief, both legal and equitable, as justice and the nature of the cause may require.

Dated: September 18, 2008 Respectfully submitted,

KELLEY DRYE & WARREN LLP

By: /s/ Philip D. Robben

William A. Escobar (admitted *pro hac vice*) Neil Merkl (admitted *pro hac vice*) Christopher C. Palermo (admitted *pro hac vice*) Philip D. Robben (admitted *pro hac vice*)

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Attorneys for Defendants Mylan Inc. (formerly known as Mylan Laboratories, Inc.), Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Defendants Mylan Laboratories Inc., Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc.'s Answer and Affirmative Defenses to Plaintiff's Complaint was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on September 18, 2008, a copy to LexisNexis File & Serve for posting and notification to all parties.